IMPORTED BLOOD/BLOOD PRODUCTS
REPORTING FORM

PRODUCT: (CHECK ALL APPLICABLE)

	Container type - please circle
_____ HUMAN WHOLE BLOOD	(TUBES BOTTLES BAGS)
_____ HUMAN RED BLOOD CELLS	(TUBES BOTTLES BAGS)
_____ HUMAN PLASMA	(TUBES BOTTLES BAGS)
_____ HUMAN SERUM	(TUBES BOTTLES BAGS)

_____ HUMAN RECOVERED PLASMA (FOR MANUFACTURING USE ONLY - INJECTABLES)

_____ HUMAN RECOVERED PLASMA (FOR MANUFACTURING USE ONLY - NONINJECTABLES)

_____ HUMAN SOURCE PLASMA (FOR MANUFACTURING USE ONLY - INJECTABLES)

_____ HUMAN SOURCE PLASMA (FOR MANUFACTURING USE ONLY - NONINJECTABLE)

CRITERIA: (PLEASE CIRCLE)

1. SPECIFICATIONS OF THE IVD MANUFACTURER FOR ACCEPTANCE OF THE HUMAN BLOOD/BLOOD PRODUCTS (21 CFR 820.50):

   SOP CONTRACTUAL AGREEMENT

2. DO THE PRODUCTS AND TESTING SPECIFICATIONS LISTED IN #1 ABOVE MATCH THE SHIPPING DOCUMENTATION? YES NO
   (Check a representative sample)

3. DEPENDING ON THE TYPE OF PRODUCT IMPORTED, DOES IT MEET THE CRITERIA FOR IMPORTATION STATED IN THE REGULATORY PROCEDURES MANUAL, CHAPTER 9, (IMPORT OPERATIONS/ ACTIONS)? YES NO (Check a representative sample)

COMMENTS: (attach additional pages as needed)

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Fax the completed questionnaire to CBER, Office of Compliance and Biologics Quality, Division of Case Management (HFM-610), Import/Export Team at (301)594-0940.